

REMARKSI. Introduction

In response to the Office Communication dated March 27, 2006, claims 23 and 41 have been amended. Claims 23-58 and 83-144 remain in the application. Entry of these amendments, and re-consideration of the application, as amended, is requested.

In the Office Communication dated March 27, 2006, the Patent Office requests further comments in support of Applicants' October 3, 2005 reply to the Office Action dated June 1, 2005. In this communication the Examiner notes that the apparatuses disclosed by Orkin et al., and Kerns et al., appear to disclose structures that are inherently capable of suspending a delivery profile while maintaining delivery of another medication. Therefore the Examiner would like Applicant to address why the apparatuses disclosed in these references are not inherently capable of performing the limitations addressed in the pending claims and more specifically, in the amendment presented in the reply of October 3, 2005.

Applicants' following comments address this issue.

II. Claimed Invention and Prior Art Rejections

Applicants' October 3, 2005 reply to the Office Action dated June 1, 2005 responded to the rejection of claims 23 and 41 under 35 U.S.C. §102(b) as being anticipated by Orkin et al.(Orkin), U.S. Patent No. 5,207,642.

In the sections below, Applicants review the claim amendments presented in the reply of October 3, 2005. Applicants then provide comments as to why the disclosures in Orkin and Kerns fail to meet the legal requirements for a finding of anticipation via inherency, particularly in view of the further amendments made herein.

## A. Claims Presented in October 3, 2005 reply to the Office Action dated June 1, 2005

The pending claims are directed to a system designed to deliver a medication using precise combinations of medication profiles. In this context, the claims recite a control system that uses an algorithm to controls a plurality of medication delivery profiles for delivering a medication from the medication reservoir to a user. In this system, the algorithm also controls a plurality of suspend functions capable of separately suspending at least one of the plurality of medication delivery

profiles so that a user can suspend a first delivery profile that delivers a medication from the medication reservoir to a user while a second delivery profile continues to deliver the medication from the medication reservoir to the user.

Independent claims 23 and 41 have been further amended hereinabove to recite embodiments of the invention where the plurality of medication delivery profiles for delivering a medication from the medication reservoir to a user includes a basal profile and a square wave bolus profile or a dual wave bolus profile. The embodiments of the invention recited in claims 23 and 41 allow a user to deliver a drug such as insulin in a manner that closely mimics the physiological profile of this protein that is observed in healthy individuals. As is known in the art, the delivery of exogenous insulin in a manner that mimics the physiological profile of this protein that is observed in healthy individuals is known to reduce the morbidity and mortality issues that are associated with diabetes.

Independent claims 89, 106 and 123 already recite these elements and/or recite further elements that are neither taught nor suggested by the Orkin and/or Kems disclosures.

B. U.S. Patent No. 5,207,642 to Orkin et al.

U.S. Patent No. 5,207,642 to Orkin et al. teaches a system for delivering fluid medications to a patient in the form of a hospital cart having a hanging IV bag filled with fluids whose output can be controlled by occluders. In the Office Communication dated March 27, 2006, the Examiner directs Applicants attention to Figure 11B in Orkin which provides a visual representation of the infusion of different types of fluids into a patient, noting that it appears that "The algorithm represented by this picture demonstrates that the apparatus is inherently capable of suspending the delivery of one fluid while maintaining delivery of another fluid."

As discussed in detail below, Applicants respectfully traverse this rejection because a detailed analysis of Orkin shows that the disclosure in this patent does not allow one of skill to determine whether or not this infusion system can employ an algorithm that is inherently capable of suspending the delivery of one fluid medication profile while maintaining delivery of another fluid medication profile. In addition, Orkin fails to teach or suggest a system that control medication profiles in this manner where the plurality of medication delivery profiles for delivering a medication from the medication reservoir to a user includes a basal profile and a square wave bolus profile or a

dual wave bolus profile (as recited in the claims amended hereinabove). Because the disclosure in Orkin does not provide disclosure sufficient to allow the artisan to determine whether or not the infusion systems are inherently capable of performing these functions as recited in the amended claims, there can be no anticipation via inherency. Applicants' specific arguments in this regard are provided below.

While neither Figure 11B in Orkin nor the specification's discussion of this Figure expressly recite the use of an "algorithm" to control drug delivery, a broad definition of an algorithm is "a step by step procedure for solving a problem or accomplishing some end". As is used in the most recent communication, this term encompasses all drug delivery schemes that hospital personnel could envision using Orkin's hanging IV cart system.

One of skill in the art may consider the disclosure in Figure 11B to be an algorithm. However, one of skill in the art would also note that a detailed analysis of this procedure for varying the flow rates of multiple fluid medications fails to teach or suggest an algorithm that controls a plurality of medication delivery profiles and a plurality of suspend functions capable of separately suspending at least one of the plurality of medication delivery profiles so that a user can suspend a first delivery profile that delivers a medication from the medication reservoir to a user while a second delivery profile continues to deliver the medication from the medication reservoir to the user. Orkin further fails to teach or suggest a system where the plurality of medication delivery profiles for delivering a medication from the medication reservoir to a user includes a basal profile and a square wave bolus profile or a dual wave bolus profile (e.g. as recited in amended claims 23 and 41).

In responding the Examiner's request, Applicants acknowledge for the sake of these arguments that perhaps it is possible that a properly designed algorithm would allow the system disclosed in Orkin to precisely control the delivery of drugs as is recited in the pending claims (if for example there were no operability issues with modifying Orkin's hanging IV cart design to accomplish this end). The disclosure in Orkin however does not tell us whether their system could be adapted to use an algorithm that controls the delivery of medications in the manner recited in the claims. For example Orkin fails to teach or suggest a system where the plurality of medication delivery profiles for delivering a medication from the medication reservoir to a user includes a basal profile and a square wave bolus profile or a dual wave bolus profile, much less the selective

suspension of such specific profiles as is recited in the claims. While it is conceivable that the system disclosed in Orkin could be manipulated to function in this manner, the disclosure in this patent simply does not place us in possession of this information. For this reason, Orkin cannot anticipate the claimed invention.

The law relating to inherency requires a disclosure to unambiguously place one in possession of the invention upon which a patent is sought in order to anticipate that invention. As noted for example in M.P.E.P. 2112, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In particular, courts find that anticipation of a claimed product cannot be predicated on mere conjecture as to the characteristics of a prior art product and instead that a claim is anticipated only if each and every element set forth in the claim is found in a prior art reference. See, e.g. *Verdegaal Bros. V. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In addition, when articulating the legal requirements for a finding of anticipation via inherency, courts state that inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." See, e.g. *Continental Can Co. v. Monsanto Co.*, 20 USPQ 2d 1746, 1749 (Fed. Cir. 1991). Instead, to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co.*, 20 USPQ 2d 1749. The disclosure in Orkin fails to do this.

As noted above, a finding of anticipation via inherency fails to meet the legal requirements for a finding of anticipation when it is predicated solely on a conjectured probability, e.g. that a prior art apparatus appears to disclose structures that are inherently capable of suspending a delivery profile while maintaining delivery of another medication. Instead, to establish inherency, it must be shown that the missing descriptive matter is necessarily present in the thing described in the reference (e.g. an algorithm that controls a plurality of medication delivery profiles including a basal profile and a square wave bolus profile or a dual wave bolus profile and a plurality of suspend functions), and that it would be so recognized by persons of ordinary skill. The disclosure in Orkin however simply does not provide this information. For this reason, the disclosure in Orkin cannot be used to render the claimed invention anticipated via inherency.

C. U.S. Patent No. 4,756,706 to Kerns et al.

The following comments respond to the Examiner's assertion that apparatuses disclosed in Kerns appear to disclose structures that are inherently capable of suspending a delivery profile while maintaining delivery of another medication.

While the term algorithm is not mentioned in the Kerns disclosure, one of skill in the art may consider some aspect of this disclosure to meet the broad definition algorithm. However, one of skill in the art would also note that a detailed analysis of this disclosure shows that fails to teach or suggest an algorithm that controls a plurality of medication delivery profiles and a plurality of suspend functions capable of separately suspending at least one of the plurality of medication delivery profiles so that a user can suspend a first delivery profile that delivers a medication from the medication reservoir to a user while a second delivery profile continues to deliver the medication from the medication reservoir to the user. Like Orkin, Kerns further fails to teach or suggest a system where the plurality of medication delivery profiles for delivering a medication from the medication reservoir to a user includes a basal profile and a square wave bolus profile or a dual wave bolus profile (e.g. as recited in independent claims 23 and 41). The disclosure in Kerns simply does not provide this information. For this reason, the disclosure in Kerns cannot be used to render the claimed invention anticipated via inherency.

As a final comment, Applicants note that the Patent Office did not assert that Kerns anticipated the claimed invention in the previous Office Action (dated June 1, 2005). Instead, this Office Action asserted that the claims were unpatentable in view of the combination of Orkin, and/or Kerns et al. (Kerns), U.S. Patent No. 4,756,706, Lebel et al. (Lebel1), U.S. Patent No. 6,562,001, Lebel et al. (Lebel2), U.S. Patent No. 6,810,290, and Rodler, U.S. Patent No. 4,457,751.

For this reason Applicants further note that because neither Orkin nor Kerns provides a teaching or suggestion that would allow (much less motivate) an artisan to generate the invention recited in the claims, neither Orkin nor Kerns, either alone or in combination, would have rendered the claimed invention obvious.

III. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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